

PharmChem, Inc.

PharmChek® Drugs of Abuse
Patch



Presented by

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PharmChek® Drugs of Abuse Patch



PharmChek® Drugs of Abuse Patch

Overview

- Sweat Collection Issues
- What is PharmChek®
- How the Sweat Patch works
- Who is using PharmChek®
- Testing Methods and Cut off Levels
- Understanding PharmChek Results
- Application Instructions
- Removing Instructions
- Additional Information

History of Drug Detection in Sweat


- Drugs known to appear in sweat:
 - methadone (1973)
 - PCP
 - amphetamines
 - nicotine
 - morphine
 - cocaine
 - phenobarbital

History of Drug Detection in Sweat

- capillary micropipettes
- "dripping"
- filter paper swab
- plastic bag over arm
- rubber gloves
- cotton body suit
- plastic body bag
- whole body washdown
- occlusive sweat patch
- sweat patch (PharmChek®) non-occlusive

PharmChek® Drugs of Abuse Patch


- The sweat patch is a non-occlusive, hypoallergenic collection device.
- The sweat patch was cleared as a collection device by FDA on October 4, 1990.
- The FDA cleared the sweat patch for the detection of cocaine, opiates and methamphetamine in 1995; for marijuana and phencyclidine in 1996.



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Patch**

How the sweat patch works


- There are two means by which the body produces sweat
 - Insensible perspiration
 - the passive uncontrolled loss of sweat from the skin
 - Sensible sweat
 - the active controlled loss from specific glands in the skin



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Patch**

How the Sweat Patch works

- The insensible perspiration is captured by the absorbent pad in the patch and analyzed for drugs.
 - approximately 300-700 ml of insensible sweat is excreted each day.
 - Approximately 2ml is absorbed in the patch each week.
- The absorbent pad is tested for the presence of drugs of abuse.



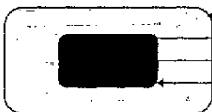
**PharmChek®Drugs of Abuse
Patch**

How the sweat patch works


- The transparent film portion of the patch is a semi-permeable membrane that allows oxygen, carbon dioxide and water vapor to pass through the patch leaving the skin underneath healthy and sterile.
- Substances of large molecular weight are trapped in the absorbent pad portion of the patch.
- Non-volatile substances from the environment cannot penetrate the transparent film from the outside

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What is PharmChek?



- Polyurethane Film
- Absorption Pad
- Unique Number
- Release Liner



- Polyurethane Film
- Release Liner
- Absorption Pad

PharmChek is a Sweat patch, worn on the skin surface, that acts as a specimen container for the non-volatile and liquid components of sweat.

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Understanding Sweat Patch Results

Detection Periods in sweat differ from those in urine, the sweat patch is a collection device designed to retain evidence of drug use.

- Results cannot be used to:
 - reflect the dose of drugs taken.
 - reflect the time of use.
 - determine if multiple small doses or one large dose of drug is ingested.
 - show when drug use occurred.

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- Currently used by long term monitoring programs:
 - Probation and Parole Agencies
 - Drug Rehabilitation Agencies
 - Corrections
 - Drug Courts

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■ Active Research Programs

- Addiction Research Center
- Center for Human Toxicology
- NIDA
- Armed Forces Institute of Pathology
- Researches in Drug Metabolism

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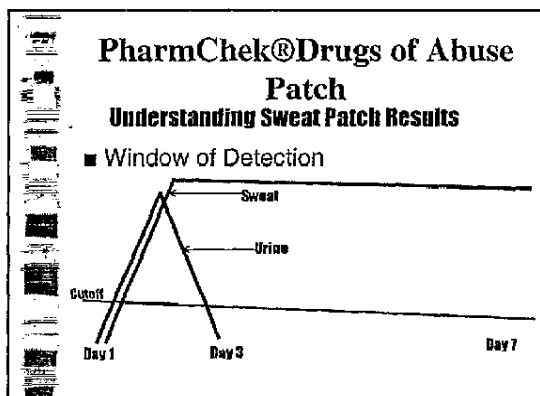
Testing Methods & Cutoff levels

Drug or Drug Class Analyte	Patch Screening	Drug or Drug Class Analyte	Patch Confirmation GC/MS
Cocaine	EIA 10 ng/ml	Cocaine Benzoylcegonine	10 ng/ml 10 ng/ml
Opiates	EIA 10 ng/ml	Heroin 6 MAM Morphine Codeine	10 ng/ml 10 ng/ml 10 ng/ml 10 ng/ml
Amphetamines	EIA 10 ng/ml	Amphetamines Methamphetamine	10 ng/ml 10 ng/ml
Marijuana	EIA 1.5 ng/ml	Marijuana	5 ng/ml
Phencyclidine	EIA 7.5 ng/ml	Phencyclidine	7.5 ng/ml

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Understanding Sweat Patch Results

- A positive result indicates drug use occurred during the time the patch was worn or 24-48 hours before the patch application.



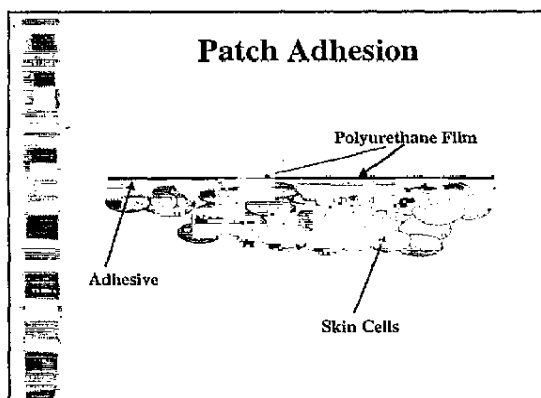
Drug Detection in Sweat

Patch Detects Parent Drug & Metabolites

- Cocaine: cocaine, ecgonine methyl ester, benzoylecgonine
- Heroin: heroin, 6-MAM, morphine
- Codeine: codeine, morphine
- Amphetamines: methamphetamine, amphetamine
- PCP: PCP
- Marijuana: THC

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Tampering

- The sweat patch is tamper evident
 - if the patch has been removed and reapplied to the skin, the patch will become cloudy.
 - If the donor has attempted to inject a substance into the patch with a hypodermic needle to try to alter the test result, it will result in a hole in the covering the sweat patch.



PharmChek® Drugs of Abuse Patch Wear Time

Patches must be worn for a minimum of 24 hours.

- Sweat patches can be worn for up to 7 days
 - if the patch is worn longer than 7 days, the test will be valid as long as there is a clear seal around the pad.

PharmChek® Drugs of Abuse Patch Inadvertent exposure

- The following will not effect the results of the test:
 - Outside contaminants
 - Marijuana smoke filled rooms will not effect the test results
- Contact with persons using drugs
 - Kissing, hugging, sexual activity etc... Will not effect the test.
- "Flushing"
 - drinking a lot of water after taking drugs will not keep the donor from having a positive test.

Drug Detection in Sweat - PharmChek®

Large-scale Field Use Evaluation

- Parallel testing with urine and PharmChek®
- Urine and PharmChek® result correlated
- 1,054 subjects
- 2,885 PharmChek® and 10,080 urine specimens

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Advantages of PharmChek®

- The distinct advantages:
 - Increased window of detection
 - Acts as a deterrent to drug abuse
 - Detects Parent Drug and Metabolites
 - Variable Removal Date
 - Quick Application and Removal
 - No urine collections
 - No Sample Substitution
 - No Sample Dilution

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■ Training Programs

- Complete training programs up to and including a collector certification program are in place.

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Application of PharmChek®

- Applying the Patch
 - Remove patch from envelope.
 - Remove backing (only the white backing with PharmChek logo).
 - Be sure the number on the patch is right side up.
 - Apply the patch onto the cleaned area of the skin.
 - gently rub the area of film around the absorption pad.
 - Remove the border and gently rub outside edge of the patch.

PharmChek® Drugs of Abuse Patch

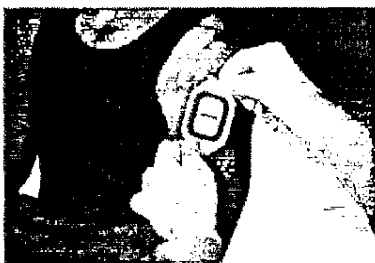
Recommended areas to wear the Patch

- Select Area to apply the patch
 - Upper or outer arm
 - Lower midriff
 - Lower back
- Cleaning Application Area
 - Aggressively Clean application area (8"x8") using the alcohol swabs provided.
 - Let area Dry 60-90 seconds

Clean Skin With Alcohol Wipe



Place Patch Over Skin



Rub Around Absorbent Pad



Remove Patch "Window Frame"



Rub Around Edge Of Patch



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Application Tips & Questions

- Have the donor flex his/her arm before applying the patch.
- The patch should not be placed on skin that has scratches, lesions, or excessive hair.
- The patch can be placed over a tattoo if no other areas are available
 - choose the lightest part of the tattoo to apply the patch.

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Chain of Custody

Complete the application section of the Chain of Custody form:

- | | |
|---|-----------------------|
| — Donor ID Number | — Patch number |
| — Donor's name (optional) | — Date |
| — Treatment Status/Reason | — Observer's Initials |
| • Random, Probable Cause, Retest, In Treatment, Medical, Other. | — Donor's Initials |

Let the donor know when he/she is to return to have the patch removed.

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Donor Instructions

- The donor should be told that if the patch appears to be coming loose, it is his/her responsibility to tell a staff person prior to the patch removal date.
- If the patch is removed early, another patch may be applied to the donor.
- The donor may perform normal activities such as work, bathing, showering and exercising, etc.

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Removal Instructions

- Supplies necessary for Removal of PharmChek®
 - Chain of Custody Form
 - The form used when applying the patch.
 - Specimen Bag
 - Disposable Plastic Tweezers and Plastic Gloves
 - Transport Bag

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Removal Tips

- Look for puncture holes
 - For best results, hold patch up to the light after removal.
- Request that the donor pull down the top edge of the patch
 - using the gloved hand, pull the patch half way down
 - using the single-use tweezers, remove the cellulose pad and place the pad in the specimen bag.
 - Affix a bar-code sticker, from the chain-of-custody form, to the outside of the specimen bag.

Donor Peels Outer Cover Of Patch Down

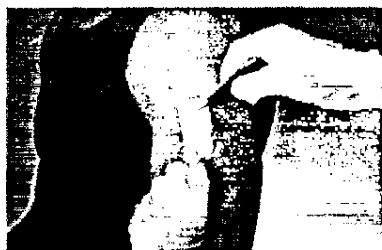


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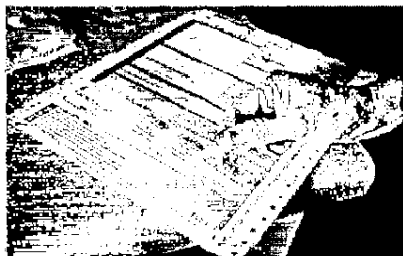
Observation after Removal

- **Confirm patch Number**
 - Compare the number on the patch with the number on the Chain of custody form.
 - The observer must initial the boxes marked "Observer's Initials".
- **Examine Patch for Tampering**
 - Look for signs of attempts to remove and re-apply
 - An uncompromised patch should have the adhesive still adhering to the skin completely surrounding the absorption pad.

Remove Absorbent Pad



Remove Barcode Label



PharmChek® Drugs of Abuse Patch Removal Information

Complete Chain of Custody

Removal

Date removed
Observer's Initials
Donor's initials

Use Information

Indicate whether the patch fell off or was taken off.
If the patch was removed before the wear period was completed, indicate the reason.
If Patch appears to have been tampered with, check the "Yes" box and indicate how.

Place Absorbent Pad In Bag



Peel Off Security Seal



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Removal Instructions

- Comments
- Medication used
- Donor signature
- Observers signature
- place the plastic specimen bag into the transport bag with the chain-of-custody form.
- Place the transport bag into the appropriate shipping envelope and send to PharmChem Laboratories for testing.

Place Barcode Label On Bag



PATCH COURT CASES UPHELD

- There have been a number of cases at the Federal and local levels challenging The Sweat Patch .
- In 3 cases in the State of CA the Patch has undergone a challenge under the Kelly Statute and one Federal challenge under the Daubert Statue which generally asks :
 - Is this a new Technology ?
 - Is this Technology accepted by the scientific community ?

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END